K090926 (pg. 1 of 1)

510(k) Summary of Safety and Effectiveness
Smith & Nephew Rail System

Submitted By:	Smith & Nephew, Inc., Orthopaedic Division 1450 Brooks Road Memphis, TN 38116
	JUN - 8 2009
Date:	March 30, 2009
Contact Person:	Laura Sejnowski, Regulatory Affairs Specialist Tel: (901) 399-5349 Fax: (901) 398-5146
Proprietary Name:	**Smith & Nephew Rail System**
Common Name:	External Fixation System
Classification Name and Reference:	21 CFR 888.3030, smooth or threaded metallic bone fixation fastener, Class II
Device Classification for Predicate Devices:	21 CFR 888.3030, smooth or threaded metallic bone fixation fastener, Class II
Device Product Code and Panel Code:	Panel: Orthopedics / 87 Product Code: KTT

Device Description:
Subject of this premarket notification is the Smith & Nephew Rail System. The Smith & Nephew Rail System is a unilateral external fixation system that offers specially designed components used in the management of lower extremity bone fractures and reconstructive, as well as corrective, orthopedic surgery. System components include rail segments, pin clamps, distraction/compression devices and associated accessories made from aluminum and stainless steel material. Like the predicate devices listed below, the subject components include a broad range of ancillary components that can be used with the rail segments *(or frame)* to provide a device customized to meet specific patient needs.

Intended Use:
The Smith & Nephew Rail System and components are intended to be used on adult or pediatric patients as required and are intended to be used for fracture fixation (open and closed); fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction; pseudarthrosis of long bones; limb lengthening; infected fractures or non-unions; and correction of long bone deformities. The Smith & Nephew Rail System and its components are for single use only.

Technological Characteristics:
The **Smith & Nephew Rail System** is similar to legally marketed devices listed below in that they share similar indications for use, are manufactured from similar materials, and incorporate similar technological characteristics.

Substantial Equivalence Information:
When compared to the predicate devices listed below, substantial equivalence is based on similarities in design features and overall indications for use.

- Smith & Nephew External Fixation System – *Unilateral (Linear) & Multilateral (Circular) Fixators and Accessories* – K994143
- Taylor Spatial Frame External Fixation System – K970748
- Heidelberg External Fixator – K970751
- Jet-X Bar System Clamps, Bar and Posts – MR Conditional – K072212
- Hex-Fix Field External Fixator - K953397

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2009

Smith & Nephew, Inc.
c/o Ms. Laura Sejnowski
1450 Brooks Road
Memphis, Tennessee 38116

Re: K090926
Trade/Device Name: Smith & Nephew Rail System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: March 30, 2009
Received: April 2, 2009

Dear Ms. Sejnowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buchman for

Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090926

Premarket Notification
Indications for Use Statement

510(k) Number (if known): _____

Device Name: Smith & Nephew Rail System

Indications for Use:

The Smith & Nephew Rail System components are intended to be used on adult or pediatric patients as required and are intended to be used for fracture fixation (open and closed); fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction; pseudarthrosis of long bones; limb lengthening; infected fractures or non-unions; and correction of long bone deformities.

Components in the Smith & Nephew Rail System are for single use only.

Prescription Use ____X____ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090926